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Oregon State Board of Pharmacy News

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No. 558: Board Member Opportunity and Staff Updates

In June 2016, there will be a pharmacist member position available on the Oregon State Board of Pharmacy. If you are interested in becoming a pharmacist Board member, candidates can be nominated by pharmacy associations or they may apply directly to the Governor's Office website at *www.oregon.gov/gov/admin/Pages/How_To_Apply.aspx.*

The Board would like to recognize Michele Cale for her years of dedicated employment and service to the citizens of Oregon. After working as an inspector/investigator for over 10 years, Michele is currently enjoying retirement, perhaps even more than the Board expected her to!

The Board welcomes a new inspector/investigator to its team. Her name is Victoria Wallace and she joined the compliance staff in December 2015. She is a 1998 graduate of the Idaho State University College of Pharmacy. When it comes to pharmacy experience, Vicki states, "You name it, I have done it – technician, intern, pharmacist in the retail pharmacy world; relief pharmacist in the independent pharmacy realm; clinical pharmacist for a rural hospital; staff and satellite pharmacist (critical care, medical/surgical, telemetry) for a nonprofit hospital; and operations management in the same nonprofit hospital setting. I never met a pharmacy job opportunity I didn't like." Vicki's leisure time activities include baking, reading for pleasure, running, mountain biking, hiking, spending time with family and friends and, of course, game nights. She is an avid Boise State University fan – Go Broncos!

No. 559: Overview of New Regulations

Last year was an active year at the Board. In 2015, the Board welcomed new staff and it has worked diligently to address and navigate the ever changing landscape facing our profession. New rules were adopted and are currently in effect. The following is an overview of some of the new regulations. As always, for questions about the rules and their application, visit the Board's website or inquire at pharmacy.board@state.or.us.

Drug Storage – Pharmacists are the drug experts and as such, it is important to recognize the safety implications of improperly stored medications. Effective January 1, 2016, all Oregon-licensed pharmacies are expected to understand and be compliant with the regulations outlined in OAR 855-041-1036. These rules establish standards for the proper storage of all drugs and outline requirements for cold storage and monitoring. Please take time to review and update your pharmacy's policies and procedures to reflect your practices of proper drug storage. To facilitate understanding of these rules, the Board created a set of frequently asked questions (FAQs), which is attached to the 2016 self-inspection forms for retail and hospital outlets; the FAQs are also available on the Board's website.

Pharmacy Practice – The 2015 Oregon Legislative Session was an active one for Oregon pharmacists. As you may know, Oregon is the second state to pass a law granting pharmacists prescriptive authority to prescribe hormonal contraceptive patches and pills, and is the first to operationalize the process. Hundreds of pharmacists have taken the training and are certified to offer this service, providing additional safe and effective access to women seeking contraceptive care. The Board has created a web page dedicated to this program, which can be accessed at *www.oregon.gov/pharmacy/Pages/ContraceptivePrescribing.aspx.*

Oregon pharmacists gained provider status as a result of 2015 House Bill 2028. This law permits pharmacists to engage in the practice of clinical pharmacy and provide patient care services to patients. The Board promulgated rules to incorporate the definitions and concepts set forth by the law, which expand collaborative practice arrangements.

Effective January 1, 2016, pharmacists can provide immunizations to patients age seven and older. The Oregon Immunization Program has updated each protocol order to address this change; please take a moment to review the protocols, as additional details have also been added to a number of the protocols. It is the pharmacist's professional responsibility to utilize appropriate judgment in all interactions with patients, and therefore, it is very important to maintain competency related to providing immunizations. You may only vaccinate to the extent of your training and knowledge, especially related to understanding proper injection site and technique, as well as holding the proper CPR certification specific to the age and population you treat. Note: A pharmacist may not continue to provide immunizations or oversee an intern immunizing if his or her CPR certification has lapsed. If a pharmacist or intern does not have a current CPR certification intended for health care providers, it must be obtained at the time of the next certification renewal.

The Board voted to extend the effective date for the automatic refill rules to allow pharmacies additional time to update their systems and provide ample opportunity for communication of the changes to patients. The Board expects compliance with these rules on or before July 1, 2016.

Drug Supply Chain – Pursuant to new federal regulations set forth by the Drug Quality and Security Act and its component, the Drug Supply Chain Security Act, the Board updated rules for manufacturers, wholesalers, and drug distribution agents. Amendments to these divisions include the following: new definitions, incorporation of outsourcing facilities as a registration type that must register with the Board as a manufacturer, a requirement for

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Discontinue Use of Chen Shwezin Sterile Drug Products, FDA Warns

In October 2015, the United States Food and Drug Administration (FDA) issued a statement alerting health care providers and patients not to use drug products intended to be sterile that were made and distributed by Chen Shwezin, Inc, dba Park Compounding Pharmacy of Westlake Village, CA, because of lack of sterility assurance. Following an FDA inspection during which investigators observed unsanitary conditions, including poor sterile production practices, FDA recommended that Park Compounding Pharmacy cease sterile operations and recall all of its non-expired sterile drug products. However, the company had refused to recall its products, according to an FDA safety alert.

At this time, FDA has not received reports of any adverse events associated with the use of products from Park Compounding Pharmacy. FDA recommends that health care providers check their medical supplies, quarantine any sterile drug products from Park Compounding Pharmacy, and not administer them to patients.

More information is available in the FDA safety alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm465582.htm.*

Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

This is the final article of a three-part series on seven persistent safety gaffes of 2014.

6) Compounded Pain Creams: High Profit Margin and Danger

Some compounding pharmacies have been heavily marketing compounded pain creams directly to consumers via unsolicited calls, suggesting that the creams are more effective and safer than oral or injectable pain medications. Many of the creams contain drugs that can cause central nervous system depression or adverse cardiac effects, and most have not been FDA-approved for use in combination with each other or for topical use. Patients are charged per ingredient, with many creams containing numerous, expensive medications. Toxicity from the creams has been reported to poison control centers, including cases of accidental child exposures and intentional use for multiple family members. Patients are often unaware of the dangers with using the creams, which include unsafe packaging in containers without child-resistant closures. ISMP is specifically concerned about some statements that may be unproven, such as the products' safe use with children. Compounded pain creams need prominent warnings on labels that describe the potential for toxicity, and physicians and pharmacists who prescribe and dispense the creams must provide patients with instructions about possible adverse effects, safe storage, and proper use. ISMP believes regulatory or licensing oversight is necessary.

7) Clear Care: Still Causing Severe Eye Injuries Five Years Later

Since early 2010, ISMP has received scores of reports of painful eye injuries from patients using CLEAR CARE® Cleaning & Disinfecting Solution for contact lenses by Alcon (formerly CIBA VISION), a Novartis company, and similar store-brand products. Hundreds more can be found on Internet listservs. Located on store shelves near other lens disinfectants and solutions, these disinfecting products differ from other commonly used solutions in that they must be used with a special lens case in order to neutralize the 3% hydrogen peroxide component of the solution over at least six hours before putting the lenses back into the eyes. However, many patients have inadvertently used the solution to soak their lenses in a standard lens case, or thought the solution was saline and instilled it directly into their eyes. This has caused severe eye burning, leading many to seek out emergency medical care for corneal burns. In 2012, Alcon made a label enhancement to warn customers to use the special lens case, but the label change has been ineffective. Neither the company nor FDA's Medical Devices division have been persuaded to make effective label improvements before permanent eye injury or blindness occurs. If the labeling and packaging cannot be improved to reduce the harm being reported, perhaps these products should be pulled from the market or available only behind the pharmacy counter.

Risk of Dose Confusion and Medication Errors With Avycaz, FDA Cautions

Confusion about the drug strength displayed on the vial and carton labels has led to some dosing errors with the intravenous antibacterial drug Avycaz™ (ceftazidime and avibactam), warned FDA in September 2015. The agency explained that Avycaz was initially approved with the vial and carton labels displaying the individual strengths of the two active ingredients (2 g/0.5 g); however, the product is dosed based on the sum of the active ingredients (2.5 g). To prevent medication errors, FDA revised the labels to indicate that each

vial contains Avycaz 2.5 g, equivalent to ceftazidime 2 g and avibactam 0.5 g, according to an FDA safety alert.

As of September 2015, FDA had received reports of three medication error cases related to confusion on how the strength was displayed on the Avycaz vial and carton labels. Two cases stated that the errors occurred during preparation of the dose in the pharmacy. The third case described concern about the potential for confusion because the strength displayed for Avycaz differs from how the strength is displayed for other beta-lactam/beta-lactamase drugs. Based on the information provided in the reports, FDA is aware that at least one of the patients received a higher-than-intended dose of Avycaz. As of September 2015, no adverse events were reported.

More details are included in the FDA safety alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463595.htm.*

US Compounding, Inc, Recalls All Lots of Sterile Compounded Products

In September 2015, US Compounding, Inc, of Conway, AR, issued a voluntary recall of all lots of sterile products aseptically compounded and packaged by the company, and that remain within expiry, because of a lack of sterility assurance. The affected sterile products were distributed nationwide to patients, providers, hospitals, and clinics between March 14, 2015, and September 9, 2015. The recall does not apply to any nonsterile compounded medications prepared by US Compounding. Providers are advised to discontinue use of the products, quarantine any unused product, and contact US Compounding to arrange the return of any unused sterile compounded products using the information provided in the FDA press release, available at *www.fda.gov/Safety/Recalls/ucm464071.htm.*

The company issued this recall out of an abundance of caution. Providers who have dispensed any sterile product distributed by US Compounding should contact patients to whom product was dispensed and notify them of this recall. A list of all sterile compounded products that have been recalled is provided on FDA's website at *www.fda.gov/Safety/Recalls/ucm464072.htm.*

FDA Investigates the Risks of Using Pain Medicine Tramadol in Young Patients

As of September 2015, FDA is investigating the use of the pain medicine tramadol in young patients because of the rare but serious risk of slowed or difficult breathing. This risk may be increased in patients treated with tramadol for pain after surgery to remove their tonsils and/or adenoids. Tramadol is not FDA-approved for use in patients aged 17 years or younger; however, data show it is being used "off-label" in the pediatric population, according to the safety alert on FDA's website, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463499.htm.*

FDA is evaluating all available information and will communicate final conclusions and recommendations to the public when the review is complete. Health care providers are encouraged to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Decreased Potency Reported in Drugs Stored in Becton-Dickinson Syringes

In September 2015, FDA expanded its alert regarding compounded or repackaged drugs stored in Becton-Dickinson (BD) general use syringes to include certain additional syringe sizes including 1 mL, 10 mL, 20 mL, and 30 mL BD syringes, and BD oral syringes. FDA's original alert applied to compounded or repackaged drugs that have been stored in 3 mL and 5 mL BD syringes. The agency expanded the alert based on BD reports that an interaction with the rubber stopper in certain lots of these syringes can cause some drugs stored in these syringes to lose potency if filled and not used immediately. BD reports that the following drugs in particular can be affected by the stoppers, but it does not know whether other drugs can be affected: fentanyl, rocuronium, neostigmine, morphine, midazolam, methadone, atropine, hydromorphone, cisatracurium, and remifentanil. This safety alert does not pertain to BD prefilled, prefillable, heparin flush, saline flush, or insulin syringes, indicates BD in an alert notice. Further, BD's alert notice also has a search tool to assist customers in determining if their lots are affected. FDA advises hospital pharmacies and staff to contact any outsourcers to determine if affected lots of BD syringes were used for compounded or repackaged products. Hospital pharmacies and staff should not administer compounded or repackaged drugs that have been stored in any of these syringes unless there is no suitable alternative available. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program.

More details are included in the FDA Safety Alert, available at *www.fda.gov/Drugs/DrugSafety/ucm458952.htm.*

MediStat Pharmacy Issues Recall of Sterile Drug Products

MediStat Pharmacy, a 503B outsourcing facility in Foley, AL, has initiated a national recall of all sterile injectable products distributed between November 1, 2014, and September 3, 2015. The recall is based on the identification of various pathogens within the compounding environment. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from MediStat, and not administer them to patients. FDA has received reports of several adverse events that are potentially associated with the drug products made by MediStat. MediStat voluntarily ceased sterile compounding operations in September 2015. FDA asks health care providers and patients to report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting program.

More details are included in an FDA press release, available at *www.fda.gov/Safety/Recalls/ucm461939.htm.*

National Association of Boards of Pharmacy Foundation
1600 Feehanville Drive
Mount Prospect, IL 60056

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third-party logistics providers to register as drug distribution agents, an update to the minimum requirements for record keeping and inventory management, and updated prohibited practices.

Links to updated rules can be found at *www.oregon.gov/pharmacy/Pages/Laws_Rules.aspx.*

No. 560: NTSB Statement – Drug Safety

Evidence That Pilots Are Increasingly Using Over-the-Counter, Prescription, and Illicit Drugs

The National Transportation Safety Board (NTSB) recently analyzed toxicology tests from 6,677 pilots who died in a total of 6,597 aviation accidents between 1990 and 2012. The results demonstrate a significant increase in the use of a variety of potentially impairing drugs.

The study found significantly increasing trends in pilots' use of all drugs, potentially impairing drugs (those with a United States Food and Drug Administration warning about sedation or behavior changes in routine use), controlled substances (CS), and illicit drugs (those defined as Schedule I by the US Drug Enforcement Administration). The final report, *Drug Use Trends in Aviation: Assessing the Risk of Pilot Impairment* (report number SS-14-01), is available on the NTSB's Safety Studies and Special Reports web page at *www.ntsb.gov/safety/safety-studies/Pages/SS1401.aspx.*

In this study, the pilot was considered to be positive for a drug if it could be qualitatively or quantitatively identified in blood or tissue; drugs identified only in urine or used as part of resuscitative efforts were excluded.

Overall, 98% of the study pilots were male and 96% were flying privately rather than for commercial purposes. The average age of study pilots increased from 46 to 57 years over the study period.

Over the course of the study, for fatally injured pilots, the following was found:

- The proportion of pilots testing positive for at least one drug increased from 10% to 40%.
- More than 20% of all pilots from 2008-2012 tested positive for a potentially impairing drug, and 6% of all pilots tested positive for more than one potentially impairing drug.
- Overall, the most common potentially impairing drug pilots had used was diphenhydramine, a sedating antihistamine (the active ingredient in many Benadryl® and Unisom® products).
- During the most recent five years studied, 8% of all pilots tested positive for CS; hydrocodone and diazepam each accounted for 20% of the positive findings.
- The percentage of pilots testing positive for marijuana use increased to about 3% during the study period, mostly in the last 10 years.

The large increase in the proportion of fatally injured pilots with evidence of potentially impairing drugs suggests an increasing risk of impairment in general aviation. Aviation is the only transportation mode in which a fatally injured operator (pilot) routinely undergoes extensive toxicology testing; no similar testing is routinely performed for fatally injured operators of boats, trains, trucks, or cars. Given the general increase in drug use in the population, it is likely that there has been a similar trend in drug use among operators across all modes of transportation.

These results highlight the importance of routine discussions between health care providers including pharmacists and their patients about the potential risks that drugs and medical conditions can create when patients are operating a vehicle in any mode of transportation.

No. 561: Oregon Prescription Drug Monitoring Program Updates

By Stephanie Vesik, MS, Oregon Health Authority – Oregon PDMP

The Oregon Prescription Drug Monitoring Program (PDMP) is pleased to inform Board licensees of updates that make utilizing the PDMP easier in their everyday practice.

The PDMP is no longer requiring a notary for account requests; instead, requesters should include a photocopy of their government-issued photo identification. This change has made the application process much easier for many, as they no longer have to take valuable time from their day to get the notary stamp.

The PDMP has opened access to the system to delegated staff of pharmacists and prescribers who also have PDMP accounts. Delegates, once the pharmacist or prescriber has linked them to his or her own account, are able to create, print, or electronically save patient reports. Many pharmacists have found that by having pharmacy technicians run patient reports they are able to provide faster, more thorough service to their customers.

Additionally, a pharmacist intern can register as a primary PDMP user. It is important to note that once an intern becomes a pharmacist, he or she must reregister with the PDMP, as registration is based on active licensure.

For questions, please contact the PDMP at *www.orpdmp.com.*

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Marc Watt, RPh - State News Editor
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